BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problems Mailbox.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
E14871 JH/JB		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/NO00/00284	31.08.2000	01.09.1999
International Patent Classification (IPC) or national classification and IPC7		
A 61 M 16/00		
Applicant		
Lovstad, Frank		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14.03.2001	11.07.2001
Name and mailing address of the IPEA/SE	Authorized officer
Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88 Telex 17978 PATOREG-S	Hélène Erikson/EÖ Telephone No. 08-782 25 00

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/NO00/00284

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:
pages 1-6 , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☒ the claims:
pages _____ , as originally filed
pages 1 , as amended (together with any statement) under article 19
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☒ the drawings:
pages 1-4 , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☐ the sequence listing part of the description:
pages _____ , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheet/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/NO00/00284

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-2	YES
	Claims		NO
Inventive step (IS)	Claims	1-2	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-2	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The most relevant documents cited in the search report are the following:

D1 US 4 196 725
D2 US 4 297 999

The claimed invention differs mainly from the cited documents in that none of the cited documents discloses a hand held, portable accessory device for a manual resuscitation unit for premature infants. The device has a self-regulating maximum pressure/volume valve connected to a conventional resuscitation equipment for blow off of excess air. Thus, the claimed invention implies an improved effect compared to prior art. Further, it is not considered obvious for a person skilled in the art to obtain the invention from the above mentioned documents.

C2HE

PCT/NO00/00284

PATENT COOPERATION TREA

21 -05- 2001

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
AMENDMENTS OF THE CLAIMS

(PCT Rule 62 and
Administrative Instructions, Section 417)

To:

Swedish Patent Office
P.O. Box 5055
S-102 42 Stockholm
SUÈDE

in its capacity as International Preliminary Examining Authority

Date of mailing (day/month/year)	
09 May 2001 (09.05.01)	
International application No.	International filing date (day/month/year)
PCT/NO00/00284	31 August 2000 (31.08.00)
Applicant	
LØVSTAD, Frank	

The International Bureau hereby transmits a copy of the amendments to the claims under Article 19 together with any accompanying statement (Rule 62).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Claudio Borton

Telephone No. (41-22) 338.83.38

Bryns Zacco as
Formerly: Bryns Patentkontor A/S
Established 1877
Enterprise No. 982702887

WIPO
34, chemin des Colombettes
1211 Geneva 20
SVEITS

Attn.:

17 January 2001

Your ref.:
Our ref.: E14871 JH/hel

RE: International Patent Application No. PCT/NO00/00284 of 31.8.00 in the name of Frank Løvstad

Sirs,

Please find enclosed a copy of our letter to IPEA/SE of January 15, 2001 with suggestion for new claims.

Yours faithfully
BRYNS ZACCO AS

Jan E. Helgerud

Enclosure:
Copy of letter
Suggestion for new claims

Postal Address	Office Address	Telephone	E-mail/Internet	Telefax	Bank Account	Post Office Account
P.O.BOX 765 SENTRUM N-0106 OSLO NORWAY	KARL JOHANSGT. 25 N-0159 OSLO NORWAY	+47 22 91 04 00	INFO@BRYNSPAT.NO WWW.BRYNSPAT.NO	+47 22 91 05 00	6001 05 66471 Kreditkassen Swift: XIANNOKK	0814 5102678

aG

Bryns Zacco as

Formerly: Bryns Patentkontor A/S
Established 1877
Enterprise No. 982702887

3171

Begäran om ändr. av ... till WIPO kan göras i detta skede 17/1 01 JW

IPEA/SE
Patent- och Registreringsverket
Boc 5055
S-102 42 STOCKHOLM
SVERIGE

Attn.:

15 January 2001

Your ref.:
Our ref.: E14871 JH/hel

International Patent Application No. PCT/NO00/00284 of 31.8.00 in the name of Frank Løvstad

Sirs,

I refer to the International Search Report, mailed December 5, 2000 and received here December 8, 2000.

The Examiner has cited US 4.196.725 of Arthur M. Gunderson and US 4.297.999 of Kitrell as documents of category X and US 5.497.767 of Sven-Gunnar Olsson, US 5.875.777 of Per-Göran Eriksson and US 5.931.162 of Klaus Christian as documents of category A.

First of all it seems necessary to recall the gist and subject matter of the present invention.

The subject matter of the present invention is a monitor and a regulation mechanism which is to be connected to existing, conventional, respiratory resuscitation unit (bag or corresponding) in order to give the treating personnel a possibility for a control of pressure, volume and frequence which they do not have today with the existing equipment.

The object according to the invention is consisting of a control box and a sensor connected to the box as indicated in the drawings.

The intention is that the object according to the invention shall have a built in rechargable battery package and it will therefore be transportable/portable.

This is a further difference in relation to the inquipment cited in the 5 publication.

Postal Address	Office Address	Telephone	E-mail/Internet	Telefax	Bank Account	Post Office Account
P.O.BOX 765 SENTRUM N-0106 OSLO NORWAY	KARL JOHANSGT. 25 N-0159 OSLO NORWAY	+47 22 91 04 00	INFO@BRYNSPAT.NO WWW.BRYNSPAT.NO	+47 22 91 05 00	6001 05 66471 Kreditkassen Swift: XIANNOKK	0814 5102678

Gunderson and Kitrell are both describing the same type of equipment. The equipment and the consept is made for use on adults where the requirement to exact volume and pressure control is not as important as it is when the problem is resuscitation of neonatal or premature infants.

These systems are further not CPU controlled. Even if Gunderson and also Kitrell have a rhythm indicating unit, probably with a rhythm in the adult area (12-30 per minute), this is only one of the aspects. Gunderson and Kitrell have no electronic diagnosis of the ratio between pressure and tidal volume (calculation of dynamic compliance) like it can be obtained according to the invention.

The expression "compliance" is a property that describes the elasticity or distensibility of the lunge and is calculated from the change in volume per unit change in pressure:

Compliance = δ volume : δ pressure.

Olsson, Eriksson and Christian are all describing the same unit which in fact is a ventilator/-respirator from Siemens Elema in Sweden.

This equipment is however not regarded as a resuscitation equipment but as treatment equipment for patients which require manual ventilatory support over time.

The present invention is intended for use together with manual operated equipment in delivery rooms. One do not find ventilators in delivery rooms because this is far too expensive. Ventilators/respirators represent equipment to which the patient is connected after the patent being stabilized with the equipment to which the device according to the invention is connected.

It is said that the equipment use manual operated resucitation bags. This is however a wrong terminology, it is not used a resucitation bag but a manual compressible balloon/bag and this is quite a different thing from a self inflating resuscitation bag. The attention is further called to the fact that resuscitation bags are not mentioned anywhere in any of the publications.

The Eriksson patent is in our opinion the closest to the consept of the invention with its idea of manual generated inspiration but the measured tidal volume is not mentioned and the user has only a certain control over pressure and flow (air stream), and it is assumed that this also is in the adult are with the allowable fluctuations.

The important feature according to the present invention is the possibility of exact control of low pressures, a quick response and control of low tidal volume with the possibility of presenting the complience (elasticity) of the lunges.

A further substantial difference between the device according to the present invention and the devices as described in the prior art, is that the device according to invention is hand held and hand operated and thus portable, I refer to the last paragraph on page 2, the 5th paragraph on page 3 and the second paragraph on page 4.

It is enclosed a suggestion for new claims which clearly should define the invention in view of the cited prior art.

Yours faithfully
BRYNS ZACCO AS

Jan E. Helgerud

Enclosure:
Amended claims

Amended Patent Claims

1.

Hand held, portable accessory device for a manual resuscitation unit for neonatal or premature infants with presice control of manual generated low tidal volumes and calculation of the compliance of the lungs for preventing volutrauma and/or barotrauma in connection with the resuscitation in the first phase of life, c h a r a c t e r i z e d b y a self regulating maximum pressure/volume valve connected to a per se conventional resuscitation equipment for blow off of excess air.

2.

Device according to claim 1 consisting of
a portable, battery driven control unit for input of maximum values for pressure or volume,
a rhythm indicating unit with the rhythm indicated through sound and light signals,
a display in the control unit which electronically is giving the ratio between pressure and tidal volume (lunge compliance),
a flow sensor for measuring pressure and air flow, giving signals to the control unit,
an electronic valve actuator for presice and rapid response for blowing off excess volume and pressure of air.

PATENT COOPERATION TREATY

0 8 DES. 2000

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
E14871 JH/JB		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/NO 00/00284	31 August 2000	1 Sept 1999
Applicant		
Lovstad, Frank		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readable form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (See Box II).

4. With regard to the **title**,

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

   [X] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/00284

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 16/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4196725 A (ARTHUR M. GUNDERSON), 8 April 1980 (08.04.80), figure	1
X	US 4297999 A (JOHN V. KITRELL), 3 November 1981 (03.11.81), abstract, figure	1
A	US 5497767 A (SVEN-GUNNAR OLSSON ET AL), 12 March 1996 (12.03.96), abstract, figure	1
A	US 5875777 A (PER-GÖRAN ERIKSSON), 2 March 1999 (02.03.99), abstract, figure	1

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search
29 November 2000

Date of mailing of the international search report
05 -12- 2000

Name and mailing address of the ISA/
Swedish Patent Office
Box 5055, S-102 42 STOCKHOLM
Facsimile No. +46 8 666 02 86

Authorized officer
Hélène Erikson/Els
Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NO 00/00284

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5931162 A (KLAUS CHRISTIAN), 3 August 1999 (03.08.99), abstract, figure -- --------	1

INTERNATIONAL SEARCH REPORT

Information on p[redacted]family members

02/11/00

International application No.
PC[redacted]O 00/00284

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4196725 A	08/04/80	NONE	
US 4297999 A	03/11/81	NONE	
US 5497767 A	12/03/96	AU 4363293 A	21/11/94
		DE 69323725 D,T	28/10/99
		EP 0621049 A,B	26/10/94
		JP 6285171 A	11/10/94
		SE 470417 B,C	21/02/94
		SE 9300364 A	21/02/94
		WO 9425718 A	10/11/94
US 5875777 A	02/03/99	AU 1048997 A	03/07/97
		EP 0803262 A	29/10/97
		EP 0865708 A	23/09/98
		JP 10033679 A	10/02/98
		SE 9601611 D	00/00/00
US 5931162 A	03/08/99	EP 0811394 A	10/12/97
		JP 10052494 A	24/02/98
		SE 9602199 D	00/00/00

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 09 May 2001 (09.05.01)	
International application No. PCT/NO00/00284	**Applicant's or agent's file reference** E14871 JH/JB
International filing date (day/month/year) 31 August 2000 (31.08.00)	**Priority date** (day/month/year) 01 September 1999 (01.09.99)
Applicant LØVSTAD, Frank	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

14 March 2001 (14.03.01)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Claudio Borton
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

RECORD COPY

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No. PCT/NO 0 0 0 0 2 8 4

International Filing Date 31 AUG. 2000 (31.08.00)

PATENTSTYRET
Styret for det industrielle rettsvern

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* E14871 JH/JB

Box No. I TITLE OF INVENTION

SUPPLEMENTARY EQUIPMENT TO A RESUSCITATION UNIT

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

LØVSTAD, Frank
Valløveien 74B
N-3150 TOLVSRØD, NORWAY

☒ This person is also inventor.

Telephone No.

Facsimile No.

Teleprinter No.

State *(that is, country)* of nationality: NORWAY

State *(that is, country)* of residence: NORWAY

This person is applicant for the purposes of: ☒ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:

☐ applicant only

☐ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

HELGERUD, Jan E.
BRYNS PATENTKONTOR A/S
P.O. Box 765, Sentrum
N-0106 OSLO, NORWAY

Telephone No. 22910400

Facsimile No. 22910500

Teleprinter No.

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a)*(mark the applicable check-boxes; at least one must be marked)*:

Regional Patent

☒ **AP** **ARIPO Patent:** **GH** Ghana, **GM** Gambia, **KE** Kenya, **LS** Lesotho, **MW** Malawi, **MZ** Mozambique, **SD** Sudan, **SL** Sierra Leone, **SZ** Swaziland, **TZ** United Republic of Tanzania, **UG** Uganda, **ZW** Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT

☒ **EA** **Eurasian Patent:** **AM** Armenia, **AZ** Azerbaijan, **BY** Belarus, **KG** Kyrgyzstan, **KZ** Kazakhstan, **MD** Republic of Moldova, **RU** Russian Federation, **TJ** Tajikistan, **TM** Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT

☒ **EP** **European Patent:** **AT** Austria, **BE** Belgium, **CH and LI** Switzerland and Liechtenstein, **CY** Cyprus, **DE** Germany, **DK** Denmark, **ES** Spain, **FI** Finland, **FR** France, **GB** United Kingdom, **GR** Greece, **IE** Ireland, **IT** Italy, **LU** Luxembourg, **MC** Monaco, **NL** Netherlands, **PT** Portugal, **SE** Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT

☒ **OA** **OAPI Patent:** **BF** Burkina Faso, **BJ** Benin, **CF** Central African Republic, **CG** Congo, **CI** Côte d'Ivoire, **CM** Cameroon, **GA** Gabon, **GN** Guinea, **GW** Guinea-Bissau, **ML** Mali, **MR** Mauritania, **NE** Niger, **SN** Senegal, **TD** Chad, **TG** Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT*(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*

☒ **AE**	United Arab Emirates	☒ **LC**	Saint Lucia
☒ **AG**	Antigua and Barbuda	☒ **LK**	Sri Lanka
☒ **AL**	Albania	☒ **LR**	Liberia
☒ **AM**	Armenia	☒ **LS**	Lesotho
☒ **AT**	Austria	☒ **LT**	Lithuania
☒ **AU**	Australia	☒ **LU**	Luxembourg
☒ **AZ**	Azerbaijan	☒ **LV**	Latvia
☒ **BA**	Bosnia and Herzegovina	☒ **MA**	Morocco
☒ **BB**	Barbados	☒ **MD**	Republic of Moldova
☒ **BG**	Bulgaria	☒ **MG**	Madagascar
☒ **BR**	Brazil	☒ **MK**	The former Yugoslav Republic of Macedonia
☒ **BY**	Belarus	☒ **MN**	Mongolia
☒ **BZ**	Belize	☒ **MW**	Malawi
☒ **CA**	Canada	☒ **MX**	Mexico
☒ **CH and LI**	Switzerland and Liechtenstein	☒ **MZ**	Mozambique
☒ **CN**	China	☒ **NO**	Norway
☒ **CR**	Costa Rica	☒ **NZ**	New Zealand
☒ **CU**	Cuba	☒ **PL**	Poland
☒ **CZ**	Czech Republic	☒ **PT**	Portugal
☒ **DE**	Germany	☒ **RO**	Romania
☒ **DK**	Denmark	☒ **RU**	Russian Federation
☒ **DM**	Dominica	☒ **SD**	Sudan
☒ **DZ**	Algeria	☒ **SE**	Sweden
☒ **EE**	Estonia	☒ **SG**	Singapore
☒ **ES**	Spain	☒ **SI**	Slovenia
☒ **FI**	Finland	☒ **SK**	Slovakia
☒ **GB**	United Kingdom	☒ **SL**	Sierra Leone
☒ **GD**	Grenada	☒ **TJ**	Tajikistan
☒ **GE**	Georgia	☒ **TM**	Turkmenistan
☒ **GH**	Ghana	☒ **TR**	Turkey
☒ **GM**	Gambia	☒ **TT**	Trinidad and Tobago
☒ **HR**	Croatia	☒ **TZ**	United Republic of Tanzania
☒ **HU**	Hungary	☒ **UA**	Ukraine
☒ **ID**	Indonesia	☒ **UG**	Uganda
☒ **IL**	Israel	☒ **US**	United States of America
☒ **IN**	India	☒ **UZ**	Uzbekistan
☒ **IS**	Iceland	☒ **VN**	Viet Nam
☒ **JP**	Japan	☒ **YU**	Yugoslavia
☒ **KE**	Kenya	☒ **ZA**	South Africa
☒ **KG**	Kyrgyzstan	☒ **ZW**	Zimbabwe
☒ **KP**	Democratic People's Republic of Korea		Check-box reserved for designating States which have become party to the PCT after issuance of this sheet:
☒ **KR**	Republic of Korea	☐	
☒ **KZ**	Kazakhstan		

Precautionary Designation Statement: In addition to the designations made above the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)*

PCT/NO 00 00284

Box No. VI PRIORITY CLAIM ☐ Further priority claim indicated in the Supplemental Box.

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is: national application: country	regional application:* regional Office	international application: receiving Office
item (1) (01.09.99) 01 September 1999	19994230	NORWAY		
item (2)				
item (3)				

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office)* identified above as item(s): 1)

** Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):*

ISA / SE

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority):*

Date *(day/month/year)* Number Country *(or regional Office)*

Box No. VIII CHECK LIST; LANGUAGE OF FILING

This international application contains the following **number of sheets**:

request	:	3
description (excluding sequence listing part)	:	6
claims	:	1
abstract	:	1
drawings	:	4
sequence listing part of description	:	
Total number of sheets	:	15

This international application is **accompanied** by the item(s) marked below:

1. ☒ fee calculation sheet
2. ☒ separate signed power of attorney
3. ☐ copy of general power of attorney; reference number, if any:
4. ☐ statement explaining lack of signature
5. ☐ priority document(s) identified in Box No. VI as item(s):
6. ☐ translation of international application into (language):
7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
9. ☒ other *(specify)*: Copy of Official Action

Figure of the drawings which should accompany the abstract: 1

Language of filing of the international application: NORWEGIAN

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Jan E. Helgerud, patent agent

For receiving Office use only

1. Date of actual receipt of the purported international application: 31 AUG. 2000 (31.08.00)
2. Drawings: ☒ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority (if two or more are competent): ISA / SE
6. ☐ Transmittal of search copy delayed until search fee is paid.

For International Bureau use only

Date of receipt of the record copy by the International Bureau: 19 SEP 2000 (19.09.00)

BLOKKDIAGRAM
TILSATS FOR ELEKTRONISK BEGRENSNING AV HÅNDVENTILASJON

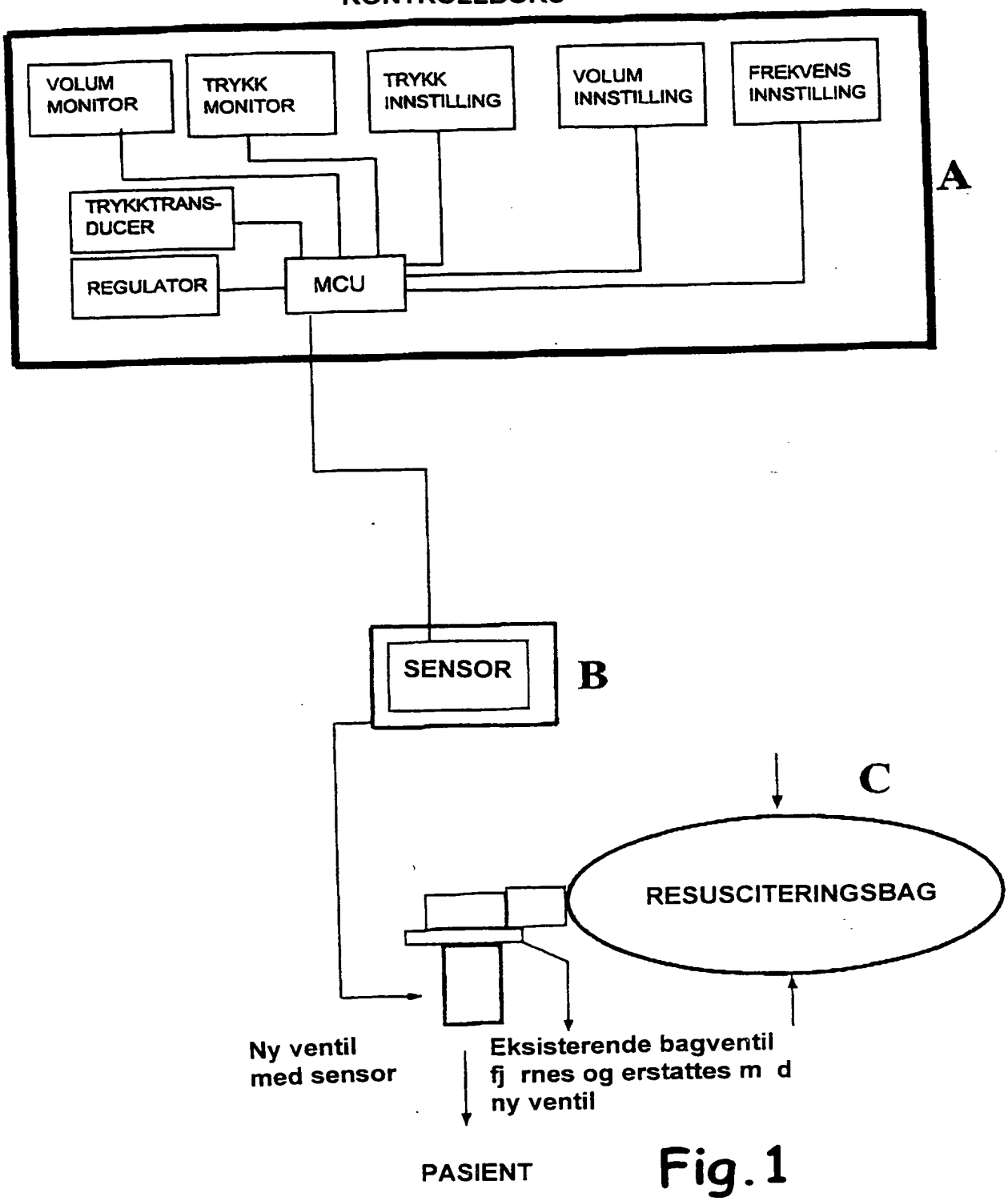


Fig. 1

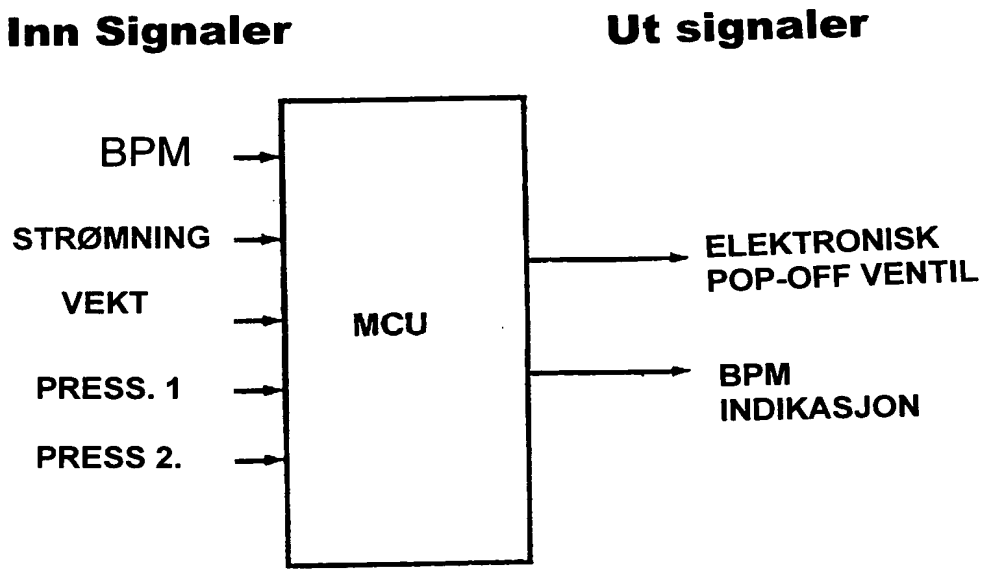
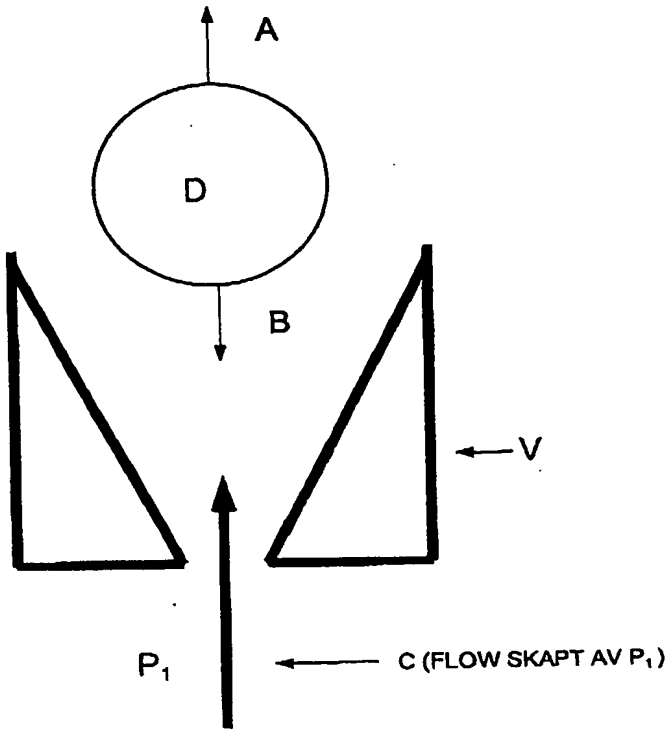

Inn Signaler
Ut signaler
BPM
STRØMNING
VEKT
PRESS. 1
PRESS 2.
MCU
ELEKTRONISK
POP-OFF VENTIL
BPM
INDIKASJON

Fig.2

PRINSIPPSKISSE FOR ELEKTROMAGNETISK REGULERING AV TRYKK/FLOW, HÅNDVENTILASJON PREMATURE



P_1 = Trykk som skal reguleres

A = Kraft som virker på D pga. C

B = Kraft som virker på D pga. magnetfelt.

Fig. 3

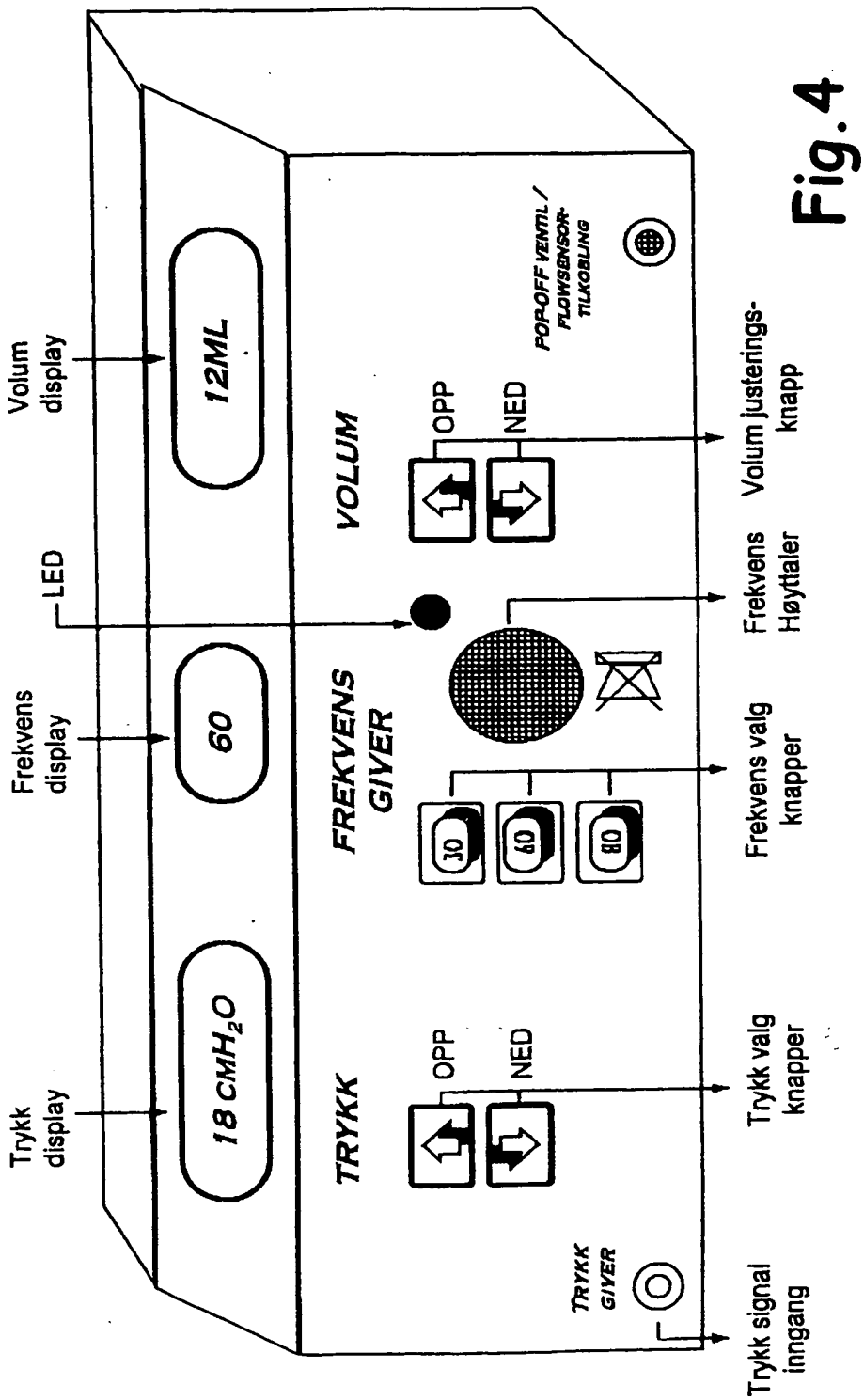

KONTROLL BOKS
Volum display
12ML
LED
Frekvens display
60
Trykk display
18 cmH2O
VOLUM
OPP
NED
POP-OFF VENTIL / FLOWSENSOR-TILKOBLING
Volum justerings-knapp
FREKVENS GIVER
Frekvens Høytaler
30
60
80
Frekvens valg knapper
TRYKK
OPP
NED
Trykk valg knapper
TRYKK GIVER
Trykk signal inngang

Fig. 4

TILLEGGSUTSTYR TIL EN RESUCITERINGSENHET

Foreliggende oppfinnelse angår et tilleggsutstyr for en resuciteringsenhet.

Nærmere bestemt angår oppfinnelsen et utstyr ment for benyttelse i forbindelse med konvensjonelt resuciteringsutstyr for å øke sikkerheten ved ventilasjonsbehandling av premature og neonatale barn.

Broncopulmonal dysplasi, BPD, er en meget vanlig og svært fryktet komplikasjon hos premature barn, altså for tidlig fødte barn, med lunger som ennu ikke er helt utviklet (surfaktant-mangel, hyalinmembran-syndrom, respiratorisk distress og så videre).

Ved mangel på surfaktant har lungene en tendens til progressive atelectaser, noe som i sin tur fører til et behov for respirator-hjelp, ofte med økende trykk-støtte.

En lunge som mangler surfaktant vil også ofte ha behov for ventilasjon med resuciteringsutstyr før barnet legges i en respirator.

For denne første fase mens barnet ventileres på bag finnes det i dag ingen sikker kontroll hverken med det trykk som benyttes ved ventileringen eller med det gassvolum barnets lunge fylles med.

Selv om dagens konvensjonelle resuciteringsbager har en såkalt sikkerhetsventil som skal utløses ved et trykk rundt 30 cm H_2O vet man i dag at dette ikke alltid er tilfelle.

Undersøkelser utført ved Tempel University i Philadelphia og også ved intensiv-avdelingen for nyfødte på Ullevål Sykehus i Oslo har vist at bager som benyttes i dag og som er generelt tilgjengelige på markedet, ikke utløser sikkerhetsventilen før trykket er over 30 cm H_2O og ved ventilasjon med frekvenser $\geq$ 80/min., ofte når trykket er $\geq$ 50 cm H_2O.

Årsaken til at premature barn utvikler BPD er såkalt baro-trauma og/eller volu-trauma, det vil si at det brukes både høyere trykk og større volum enn det lungene til de minste premature barn tåler. Det er i dag mye som tyder på at dette skjer allerede på føde-avdelingen eller eventuelt i operasjonsstuen hvis keisersnitt må gjennomføres, når barnet har behov for resucitering.

Det er i løpet av årene kommet tallrike publikasjoner, blant annet fra de ovenfor nevnte medisinske sentra, som fremhever betydningen av å redusere baro-trauma i den neonatale periode for å forhindre kronisk lungesykdom. Man regner med at dette problem plager ca. 37 % av små for tidlig fødte barn som har kommet seg efter alvorlig respiratorisk distress syndrom ved fødselen.

Man søker derfor i dag å minimalisere trykk-eksponeringen overfor barn i alle faser ved den neonatale behandling.

Det er derfor i dag et uttrykt behov i de kretser som ønsker å gjøre behandling, derunder resucitering, av premature og neo-natale barn, så sikker som mulig og det er derfor behov for et utstyr som kan benyttes sammen med dagens konvensjonelle resuciteringsbags for å sikre mot baro-trauma og volu-trauma ved hurtig og sikkert å reagere ved overskridelse av på forhånd bestemte maksimal-verdier.

Foreliggende oppfinnelse har til hensikt å avhjelpe manglene ved den kjente teknikk og er i prinsippet basert på følgende tankegang.

Ved resucitering av nyfødte/for tidlig fødte vil man i dag benytte en håndventilasjonsbag. Ved for tidlig fødsel fra og med 24. svangerskapsuke og opp til 36. uke, er barnets luftveier som antydet ovenfor ikke helt ferdig utviklet og disse barn som ikke har egen respirasjon ennu vil ventileres manuelt med en ventilasjonsbag de første viktige minuttene efter fødselen.

På grunn av at luftveiene som nevnt ovenfor ikke er helt ferdig utviklet er de også ekstremt ømfintlige idet de mangler den så viktige elastisitet, i det vesentlige på grunn av naturlige på overflaten virkende stoffer, surfaktanter, som bidrar sterkt til elastisiteten.

Ved dagens midler for den umiddelbare håndventilering er det en kjennsgjerning at man ikke har full kontroll over de trykk, volumer og frekvenser som benyttes. Når et barn i en slik situasjon ikke puster mister personalet ofte tidssansen i en viss grad, også godt øvet personale. Dette kan ubevisst føre til en alt for høy ventileringsfrekvens.

Litt avhengig av stedlige rutiner hender det at det kobles inn et mekanisk manometer for å måle det trykk man ventilerer det nyfødte barn med.

Trykket måles ved tilkoblingen mellom bagen og pustemasken.

Problemet ved denne teknologi er imidlertid at de benyttede manometere ikke på langt nær responderer hurtig nok og at man derfor ikke får noe reelt bilde av det trykk som egentlig hersker.

Kobler man inn en digital trykkmåler med hurtigere respons vil man se et betydelig høyere trykk når frekvensen stiger.

Man har imidlertid heller ingen begrensning av trykket hvis man skulle være litt uforsiktig/uerfaren og derved komme i skade for å ventilere med for høyt trykk.

Til slutt mangler det kontroll når det gjelder det volum som avgis, man skal her holde for øyet at det er snakk om volumer helt ned til 2 til 3 ml.

Det finnes på markedet i dag overtrykksventiler som kan settes på ventilasjonsbagen. Det dreier seg her om mekaniske fjærventiler som har svært dårlig frekvens-respons, det vil si at de for det første er svært unøyaktige hva trykket angår, derefter at utløsnings-trykket øker ved frekvenser over 40/min.

På grunn av disse faktorer slik de er oppsummert ovenfor har man opplevd tilfeller med ventilasjonsfrekvenser helt opp til 120/min.

Alle disse tingene vil hver for seg og selvfølgelig i alt for stor grad sammen føre til overventilering (overstrekking av barnets luftveier). Dersom en slik overstrekking av de lite elastiske deler av luftveiene skjer vil disse ytterst små luftveier (alveoler) ikke returnere til den opprinnelige form men istedet gå over til en plastisk tilstand, noe som i verste fall kan føre til dødsfall og i beste fall kan føre til at barnet blir liggende i respirator i dager/uker/måneder.

Som nevnt ovenfor er det derfor et uttrykt ønske i de kretser som arbeider med premature og neo-natale barn å ha til disposisjon et enkelt produkt som på sikker måte begrenser trykk og volum og som samtidig gir klare anvisninger hva angår den ventileringsfrekvens som skal benyttes.

Foreliggende oppfinnelse har således til hensikt å utvikle et slikt utstyr som i tillegg raskt og hurtig bør kunne kobles til det eksisterende resuciteringsutstyr.

Idéen bak foreliggende oppfinnelse er å utvikle en enkel monitor som registrerer og regulerer det trykk og volum av luft som gies premature barn ved hånd-ventilasjon. Denne monitor må ha en ekstern sensor som kobles til håndventilsbagen (eller belgen) som benyttes, mellom denne og pustemasken.

Når volumet eller trykket når en gitt verdi skal utstyret "blåse av" det overskytende.

En mulighet for gjennomføring av dette er å arbeide med en elektromagnetisk trykk-reguleringsventil.

Ventilen er med fordel selvregulerende, det vil si at kun et signal til ventilen skal være nok til at den utfører den ønskede regulering.

I henhold til dette angår foreliggende oppfinnelse et tilleggsutstyr for en enhet for resucitering av nyfødte/for tidlig fødte barn, for å forhindre baro-trauma og/eller volu-trauma med efterfølgende utvikling av broncopulmonal dysplasi, og denne anordning karakteriseres ved en selv-regulerende maksimaltrykk-/-volumventil mellom et i og for seg konvensjonelt resuciteringutstyr og den tilhørende pustemaske, eller endotrakeal-rør (ET Tube) for avblåsning av overskytende luftmengde, og med en tilkoblet, frekvens-innstillbar, rytmegivende metronom.

Oppfinnelsen skal forklares nærmere ved hjelp av de vedlagte figurer der:

- figur 1 viser et blokk-diagram for elektronisk begrensning av håndventilasjon;
- figur 2 viser en skisse for en utførelsesform av gangen for de elektroniske signaler;
- figur 3 viser en prinsipp-skisse for en elektromagnetisk regulerings-ventil av trykk/flow; og
- figur 4 viser et mulig utseende av en kontroll-boks.

I figurene står MCV for "Micro Control Unit". I figur 2 står BPM for åndefrekvensen "Breath Per Minute".

Idéen bygger på prinsippet om å sette inn en kontroll-boks som skal måle flow og trykk og derfra å beregne inspirert volum og trykk. Når de riktige volumer eller trykk er oppnådd skal det drivende trykk reduseres slik at inspirasjon termineres.

Som nevnt ovenfor er dette tenkt som et komplement til kjent håndventilasjonsutstyr av premature og neo-natale pasienter idet premature barn har et helt spesielt behov for en nøyaktig kontroll av ventilasjonen for at de ovenfor skisserte skader skal kunne unngås.

I prinsippet kan man tenke seg å anvende en hvilken som helst hurtig-virkende, selv-styrende, elektronisk betjent ventil men i en foretrukken utførelsesform anvendes elektro-magnetisme som en påvirkende kraft på en magnetisk sensitiv gjenstand for at denne skal kunne stenge et strømløp med ønsket kraft og derved å kunne regulere strømmen gjennom dette. Som nevnt er det ønskelig at ventilen er selvregulerende, det vil si at kun et signal til ventilen skal være nok for at den skal kunne utføre regulerings-oppgavene.

Man kan også tenke seg en sollenoid-ventil.

Kontroll-boksen som antydet i figur 4 inneholder en mikro-prosessor som bearbeider de signaler som mottas fra en flow-sensor og en trykk-sensor. Brukeren må selv definere den ønskede trykk- og volum-begrensning innenfor et begrenset område idet betingelsene må fastlegges på stedet alt efter omstendighetene rundt fødselen. De mottatte signaler styrer så mikro-prosessorens videre bearbeiding av signalene.

Som nevnt ovenfor spiller frekvensen en meget stor rolle og innenfor de gitte omstendigheter rundt fødselen bør det være mulig å kunne forhåndsinnstille for eksempel høyst 3 frekvenser som så må overholdes ved den efterfølgende hånd-ventilering.

Figur 1 viser generelt de enheter som trenges for å kunne erstatte en eksisterende bagventil med en ventil tilhørende utstyret ifølge oppfinnelsen.

Volum og trykk overvåkes og holdes mot innstilt trykk og volum samtidig som den valgte frekvens gies.

Figur 2 viser i litt større detalj en mulig oppkobling til data-enheten hvor signalene bearbeides og skissen antyder også utgående signaler.

Figur 3 viser en mulig utførelsesform av en ventil i utstyret ifølge oppfinnelsen. Strømmen C under et trykk P1 virker mot et lukke-legeme D med kraften A mens elementet D holdes i ventilen V ved hjelp av et pålagt magnetfelt.

Til slutt viser figur 4, som nevnt ovenfor, en kontrollboks som i tillegg til trykk også inneholder en innstillingsmulighet for ønsket ventileringsfrekvens og -volum ut fra den gitte kroppsvekt og der også flow-sensor signaler går inn.

Boksen er videre utstyrt med en form for frekvens-indikator, for eksempel ved hjelp av en høyttaler og/eller lysdiode som vist i figuren.

Rent generelt består utstyret av 2 deler, en flowsensor og en kontrollboks med trykkføler og betjeningsknapper for innstilling av ønsket tidalvolum, frekvens og trykk.

Frekvensen skal angis gjennom en "metronom" eller pacer som gir brukeren lyd (tikker) og lyssignal (diode). Det er viktig at det er få frekvensvalg, for eksempel 30-60-80.

Volum kan innstilles enten ved å velge, med en betjeningsknapp, pasientens kroppsvekt og derigjennom få et på forhånd programmert volum/kg (for eksempel 5 ml/kg, (eller ved å velge antall ml tidalvolum direkte som en verdi. Det siste er kanskje det mest anvendelige fordi det første alternativet i stor grad begrenser utstyrets bruksområde.

Maks inspiratorisk trykk velges gjennom egen betjeningsknapp. Det valgte makstrykk skal da være styrende for regulering i regulatoren.

Trykk og volum skal være likeverdige regulerende parametre (det som oppnås først).

Ved hjelp av oppfinnelsens tilleggsutstyr vil man kunne øke sikkerheten ved håndventilasjon av neonatale og premature barn i vesentlig grad.

Utstyret er lett å produsere, det er varierbart alt efter de omstendigheter som foreligger ved fødselen, utstyret vil gi hurtig respons og inneholder få detaljer som kan skades eller ødelegges.

Et vesentlig trekk er at utstyret kan kobles til alle de i dag eksisterende hånd-ventilasjonsbager da slikt utstyr forøvrig har standard tilkoblingsenheter.

En stor fordel er at utstyret er enkelt i bruk og at det er rimelig å anskaffe og lett å vedlikeholde.

Patentkrav

Tilleggsutstyr for en resuciteringsenhet for nyfødte/for tidlig fødte barn for å forhindre baro-trauma og/eller volu-trauma med utvikling av broncopulmonal dysplasi, karakterisert ved en selv-regulerende maksimaltrykk-/-volumventil mellom et i og for seg konvensjonelt resuciteringutstyr og den tilhørende pustemaske, eller endotrakeal-rør (ET Tube), for avblåsning av overskytende luftmengde, og med en tilkoblet, frekvens-innstillbar, rytmegivende metronom.

Sammendrag

Tilleggsutstyr for en resuciteringsenhet for nyfødte/for tidlig fødte barn for å forhindre baro-trauma og/eller volu-trauma med utvikling av broncopulmonal dysplasi, omfatter en selv-regulerende maksimaltrykk-/-volumventil mellom en i og for seg konvensjonell resuciteringbag og den tilhørende pustemaske, for avblåsning av overskytende luftmengde, og med en tilkoblet, frekvens-innstillbar, rytmegivende metronom.

(Figur 1)

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

16 MAR 2001 **PCT**

To:

Bryns Patentkontor A/S
P.O. Box 765, Sentrum
N-0106 OSLO

NOTIFICATION OF RECEIPT OF DEMAND BY COMPETENT INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

(PCT Rules 59.3(e) and 61.1(b), first sentence and Administrative Instructions, Section 601(a))

Date of mailing *(day/month/year)*	14-03-2001
Applicant's or agent's file reference: E14871 JH/JB	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/NO00/00284	31-08-2000	01-09-1999

Applicant
Lovstad, Frank

1. The applicant is hereby **notified** that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

   14-03-2001

2. This date of receipt is:

   [X] the actual date of receipt of the demand by this Authority (Rule 61.1(b)).

   [ ] the actual date of receipt of the demand on behalf of this Authority (Rule 59.3(e)).

   [ ] the date on which this Authority has, in response to the invitation to correct defects in the demand (Form PCT/IPEA/404), received the required corrections.

3. [ ] **ATTENTION:** That date of receipt is **AFTER** the expiration of 19 months from the priority date. Consequently, the election(s) made in the demand does (do) not have the effect of postponing the entry into the national phase until 30 months from the priority date (or later in some Offices) (Article 39(1)). Therefore, the acts for entry into the national phase must be performed within 20 months from the priority date (or later in some Offices) (Article 22). For details, see the *PCT Applicant's Guide*, Volume II.

   [ ] *(If applicable)* This notificaton confirms the information given by telephone, facsimile transmission or in person on:

4. Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

Name and mailing address of the IPEA/	Authorized officer
Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88 Telex 17978 PATOREG-S	Telephone No. 08-782 25 00 Jan-Erik Karlsson

Form PCT/IPEA/402 (July 1998)

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 March 2001 (08.03.2001)

PCT

(10) International Publication Number
WO 01/15761 A1

(51) International Patent Classification[7]: A61M 16/00

(21) International Application Number: PCT/NO00/00284

(22) International Filing Date: 31 August 2000 (31.08.2000)

(25) Filing Language: Norwegian

(26) Publication Language: English

(30) Priority Data:
19994230 1 September 1999 (01.09.1999) NO

(71) Applicant and
(72) Inventor: LØVSTAD, Frank [NO/NO]; Valløveien 74B, N-3150 Tolvsrød (NO).

(74) Agent: HELGERUD, Jan, E.; Bryns Patentkontor A/S, P.O. Box 765, Sentrum, N-0106 Oslo (NO).

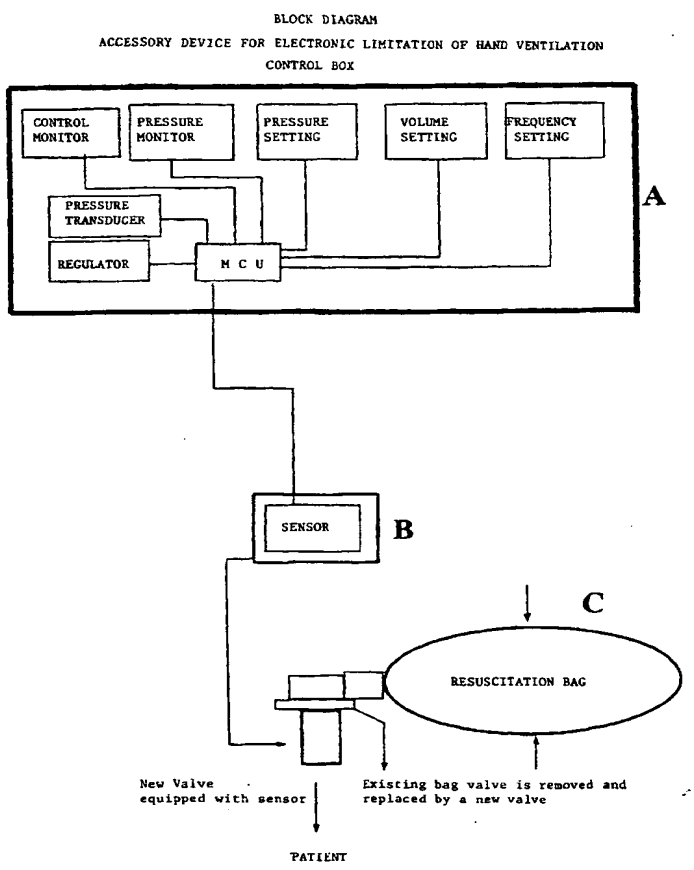
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*
— *With amended claims.*

[Continued on next page]

(54) Title: AN ACCESSORY DEVICE FOR A RESUSCITATION UNIT



(57) Abstract: An accessory device for a resuscitation unit for neonatal or premature infants for preventing baro-trauma and/or volu-trauma, and the subsequent development of broncopulmonary dysplasia, comprises a self-regulating maximum pressure/volume valve between a conventional resuscitation bag per se and its associated face mask, for blow-off of excess air volume, and having a frequency-adjustable, rhythm-indicating metronome connected thereto.

WO 01/15761 A1

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

AN ACCESSORY DEVICE FOR A RESUSCITATION UNIT

The present invention relates to an accessory device for a resuscitation unit.

More precisely, the invention relates to a device for use in connection with conventional resuscitation equipment to enhance safety during the ventilation treatment of premature and neonatal infants.

Broncopulmonary dysplasia, BDP, is a highly common and dreaded complication in premature infants, i.e., infants born before term, whose lungs are not yet fully developed (surfactant deficiency, hyaline membrane syndrome, respiratory distress and so forth).

When there is surfactant deficiency, the lungs have a tendency to develop progressive atelectasis, which in turn results in the need for respirator support, often with increasing pressure support.

Often, a lung deficient in surfactants will also require ventilation by means of resuscitation equipment before the infant is placed in the respirator.

For this first phase whilst the infant is ventilated by bag, there is today no reliable control of the pressure used during the ventilation or of the gas volume with which the infant's lungs are filled.

Although the conventional resuscitation bags that are currently available have a so-called safety valve that should be released at a pressure of about 30 cm H_2O, it is known today that this does not always happen.

Studies carried out at Temple University in Philadelphia and also at the neonatal intensive care unit at Ullevål Hospital in Oslo have shown that the bags used today and which are generally available on the market, do not release the safety valve until the pressure is over 30 cm H_2O, and at ventilation of frequencies $\geq$ 80/min, release often only takes place when the pressure is $\geq$ 50 cm H_2O.

The reason that premature infants develop BPD is so-called baro-trauma and/or volu-trauma, i.e., that both the pressure and the volume used are greater than the lungs of the smallest premature infants can withstand. Today, there is much to suggest that the infant suffers these traumas as early as in the delivery ward, or perhaps in the operating

theatre if delivery by Caesarean section is required, when the infant is in need of resuscitation.

Over the years a great number of publications have appeared, including some from the aforementioned medical centres, that stress the importance of reducing baro-trauma in the neonatal period in order to prevent chronic lung disease. It is believed that this problem affects about 37% of small, premature infants that have recovered after severe respiratory distress syndrome at birth.

Today, therefore, efforts are being made to minimise the pressure exposure to which infants are subjected in all phases of neonatal treatment.

Consequently, there is an explicit need among those wishing to make the treatment, including resuscitation, of premature and neonatal infants, as safe as possible, and therefore a device is required that can be used together with today's conventional resuscitation bags to safeguard against baro-trauma and volu-trauma by reacting both quickly and reliably when predetermined maximum values are exceeded.

The object of the present invention is to remedy the deficiencies of the prior art, and the invention is in principle based on the following ideas.

Today, in the resuscitation of neonatal or premature infants, a manual ventilation bag is used. In premature births from 24 weeks of gestation to 36 weeks inclusive, the infant's airways, as mentioned above, are not fully developed, and these infants, who cannot yet breathe unaided, will be hand-ventilated with a ventilation bag in the first important minutes after birth.

Because the airways, as already mentioned, are not fully developed, they are also extremely sensitive as they lack the essential elasticity, primarily because the natural surface-active agents, surfactants, which contribute greatly to the elasticity are lacking.

It is a fact that in today's means for immediate hand ventilation, there is no full control of the pressure, volumes and frequencies that are used. When an infant in such a situation does not breathe, the staff often lose their sense of time to a certain degree, even highly experienced staff. This may unconsciously result in an excessively high ventilation frequency.

Depending somewhat on local routines, a mechanical manometer may be connected to measure the pressure with which the newborn infant is ventilated.

The pressure is measured at the connection between the bag and the face mask.

However, the problem with this technology is that the manometers used do not react anywhere near quickly enough, and therefore the medical personnel have no true picture of the pressure that in fact prevails.

If a faster reacting digital pressure recorder is connected, a substantially higher pressure will be seen when the frequency rises.

However, there is also no limit on the pressure if the staff are a little careless or inexperienced and may thus inadvertently ventilate using an excessively high pressure.

Lastly, there is no control as regards the volume delivered. Here it should be remembered that the volumes involved are as little as 2 to 3 ml.

On today's market there are pressure relief valves that can be fitted on the ventilation bag. These are mechanical spring valves which have a very poor frequency response, i.e., in the first place, they are highly inaccurate as regards the pressure and, in the second place, the pressure released increases at frequencies above 40/min.

On account of these factors as they are summarised above, there have been cases of ventilation frequencies as high as 120/min.

All these factors separately and, of course, even more so in combination, will result in hyperventilation (an overstretching of the infant's airways). If there is such an overstretching of the rather inelastic parts of the airways, these extremely small airways (alveoli) will not return to their original form but will instead pass into a plastic state, which at worst can result in death, and at best can result in the child remaining in a respirator for days, weeks or even months.

As mentioned above, it is therefore an express wish among those who work with premature and neonatal infants to have at their disposal a simple product that in a simple manner limits the pressure and volume and which at the same time gives clear indications as regards the ventilation frequency that is to be used.

Thus, the object of the present invention is to develop a device this kind that also should be capable of being connected promptly and readily to existing resuscitation equipment.

The idea behind the present invention is to develop a simple monitor that registers and regulates the pressure and volume of air that is given to premature infants by hand ventilation. This monitor must have an external sensor that is connected to the manual ventilation bag (or the bellows) used, between the bag and the face mask.

When the volume or the pressure reaches a given value the device should "blow off" the excess.

One way of doing this is to work with an electromagnetic pressure control valve.

Advantageously, the valve is self-regulating, i.e., just one signal to the valve will be sufficient to ensure that it carries out the required control.

Accordingly, the present invention relates to an accessory device for a unit for the resuscitation of newborn or premature infants for the purpose of preventing baro-trauma and/or volu-trauma and the subsequent development of broncopulmonary dysplasia, and this device is characterised by a self-regulating maximum pressure/volume valve between conventional resuscitation equipment per se and the associated face mask, or endotracheal tube (ET Tube), for blow-off of excess air volume, and having a frequency-adjustable, rhythm-indicating metronome connected thereto.

The invention will be explained in more detail with the use of the attached figures, wherein:

- Figure 1 is a block diagram of the electronic limitation of hand ventilation;
- Figure 2 is an outline of an embodiment of the pathway for the electronic signals;
- Figure 3 is a schematic diagram of an electromagnetic pressure/flow control valve; and
- Figure 4 shows what a control box may look like.

In the figures the letters MCU stand for "Micro Control Unit". In Figure 2 the letters BPM stand for the breathing frequency "Breath per Minute".

The inventive idea is based on the principle of installing a control box that is to measure flow and pressure and on the basis thereof compute inhaled volume and pressure. When the correct volumes or pressures have been reached, the operating pressure is to be reduced so that inspiration is terminated.

As mentioned above, this is intended as a complement to the known manual ventilation equipment for premature and neonatal patients, as premature infants have a special need for accurate control of the ventilation in order to prevent the damage outlined above from occurring.

In principle, it is possible to use any rapid-action, self-regulating electronically operated valve, but in a preferred embodiment electromagnetism is used as an actuating force on a magnetically sensitive object to enable the object to close a flow path with desired force and thus be able to control the flow therethrough. As mentioned, it is desirable that the valve should be self-regulating, i.e., that just one signal should be sufficient to enable it to carry out its control functions.

It is also possible to use a solenoid valve.

The control box, as indicated in Figure 4, contains a micro-processor that processes the signals it receives from a flow sensor and a pressure sensor. The user himself must define the desired pressure and volume limits within a restricted range, as the conditions must be established instantly, according to all the circumstances of the birth. The received signals then control the further processing of the signals by the micro-processor.

As mentioned above, frequency plays a very important role, and within the given circumstances surrounding the birth it should be possible to pre-set, for example, at most three frequencies which then must be observed during the subsequent hand ventilation.

Fig. 1 shows in general the units required to be able to replace an existing bag valve with a valve belonging to the device according to the invention.

Volume and pressure are monitored and maintained against set pressure and volume at the same time as the selected frequency is given.

Figure 2 shows in slightly greater detail a possible connection to the computer unit where the signals are processed. Outgoing signals are also indicated in the drawing.

Figure 3 shows a possible embodiment of a valve in the device according to the invention. Flow C under a pressure P1 acts against a closing body D with force A whilst the element D is held in the valve V by means of an applied magnetic field.

Lastly, Figure 4 shows, as mentioned above, a control box which in addition to pressure also contains a setting means for desired ventilation frequency and volume based on the given body weight and in which also flow sensor signals enter.

The box is also equipped with a form of frequency indicator, for example, by using a loudspeaker and/or light emitting diode as shown in the figure.

Broadly speaking, the device consists of two parts, a flow sensor and a control box with equipped with a pressure sensor and control buttons for setting the desired tidal volume, frequency and pressure.

The frequency is to be indicated by a "metronome" or pacer that provides the user with sounds (ticks) and light signals (diode). It is important that there are few frequency choices, for example, 30-60-80.

Volume can be set either by choosing, with the use of a control button, the body weight of the patient, and in so doing be given a pre-programmed volume/kg (for example, 5 ml/kg), or by choosing a number ml tidal volume directly as a value. The last alternative is perhaps the most useful because the first alternative substantially limits the area of application of the equipment.

Maximum inspiratory pressure is selected by means of a separate control button. The selected maximum pressure should then be guiding for the control of the regulator.

Pressure and volume should be equally important controlling parameters (that reached first).

By means of the inventive accessory device, it will be possible to greatly enhance safety during hand ventilation of neonatal and premature infants.

The device is easy to make, and it can be varied according to the circumstances surrounding the birth. It will provide a rapid reaction and contain few details that can be harmed or destroyed.

An essential feature is that the device can be connected to all hand ventilation bags in existence today as devices of this kind have standard connection units.

A major advantage is that the equipment is easy to use and that it is inexpensive to procure and easy to maintain.

Patent claim

An accessory device for a resuscitation unit for neonatal or premature infants for preventing baro-trauma and/or volu-trauma and the subsequent development of broncopulmonary dysplasia, characterised by a self-regulating maximum pressure/volume valve between conventional resuscitation equipment per se and its associated face mask, or endotracheal tube (ET Tube), for blow-off of excess air volume, and having a frequency-adjustable, rhythm-indicating metronome connected thereto.

AMENDED CLAIMS

[received by the International Bureau on 17 January 2001 (17.01.01);
original claim 1 replaced by new claims 1 - 2 (1 page)]

1.

Hand held, portable accessory device for a manual resuscitation unit for neonatal or premature infants with presice control of manual generated low tidal volumes and calculation of the compliance of the lungs for preventing volutrauma and/or barotrauma in connection with the resuscitation in the first phase of life, c h a r a c t e r i z e d b y a self regulating maximum pressure/volume valve connected to a per se conventional resuscitation equipment for blow off of excess air.

2.

Device according to claim 1 consisting of
a portable, battery driven control unit for input of maximum values for pressure or volume,
a rhythm indicating unit with the rhythm indicated through sound and light signals,
a display in the control unit which electronically is giving the ratio between pressure and tidal volume (lunge compliance),
a flow sensor for measuring pressure and air flow, giving signals to the control unit,
an electronic valve actuator for presice and rapid response for blowing off excess volume and pressure of air.

BLOCK DIAGRAM

ACCESSORY DEVICE FOR ELECTRONIC LIMITATION OF HAND VENTILATION

CONTROL BOX

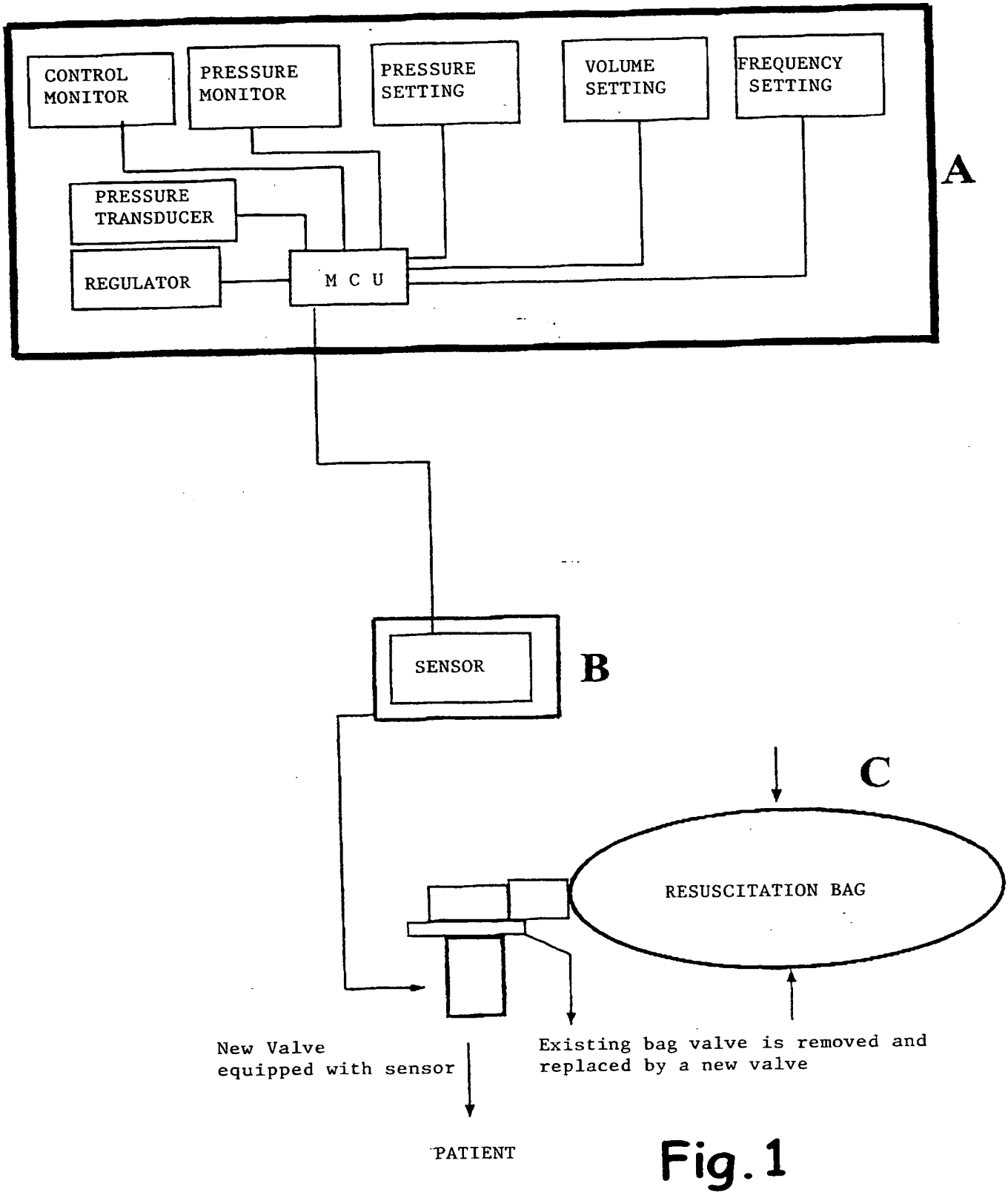


Fig. 1

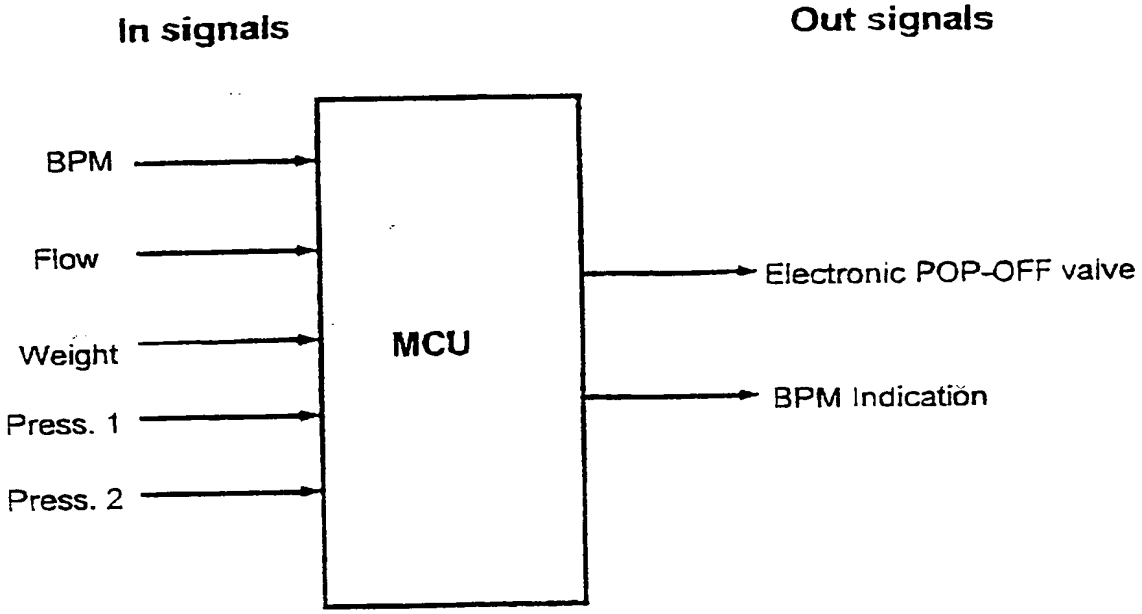
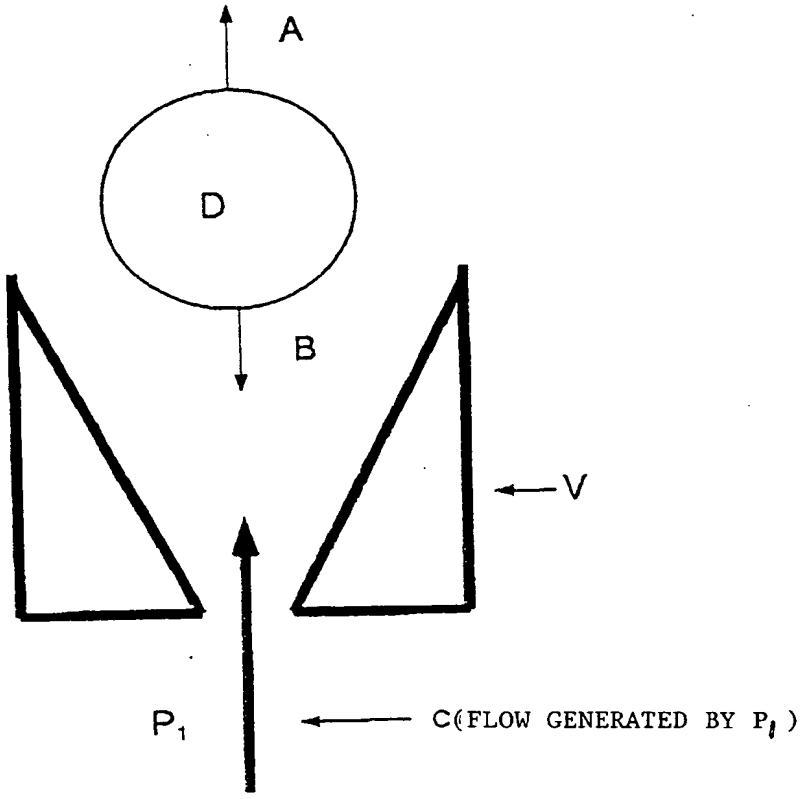

In signals
Out signals
BPM
Flow
Weight
Press. 1
Press. 2
MCU
Electronic POP-OFF valve
BPM Indication

Fig.2

SCHEMATIC DIAGRAM OF ELECTROMAGNETIC CONTROL OF PRESSURE/FLOW, HAND VENTILATION - PREMATURE



P_1 = PRESSURE TO BE CONTROLLED

A = FORCE ACTING ON D BECAUSE OF C

B = FORCE ACTING ON D BECAUSE OF MAGNETIC FIELD

Fig.3

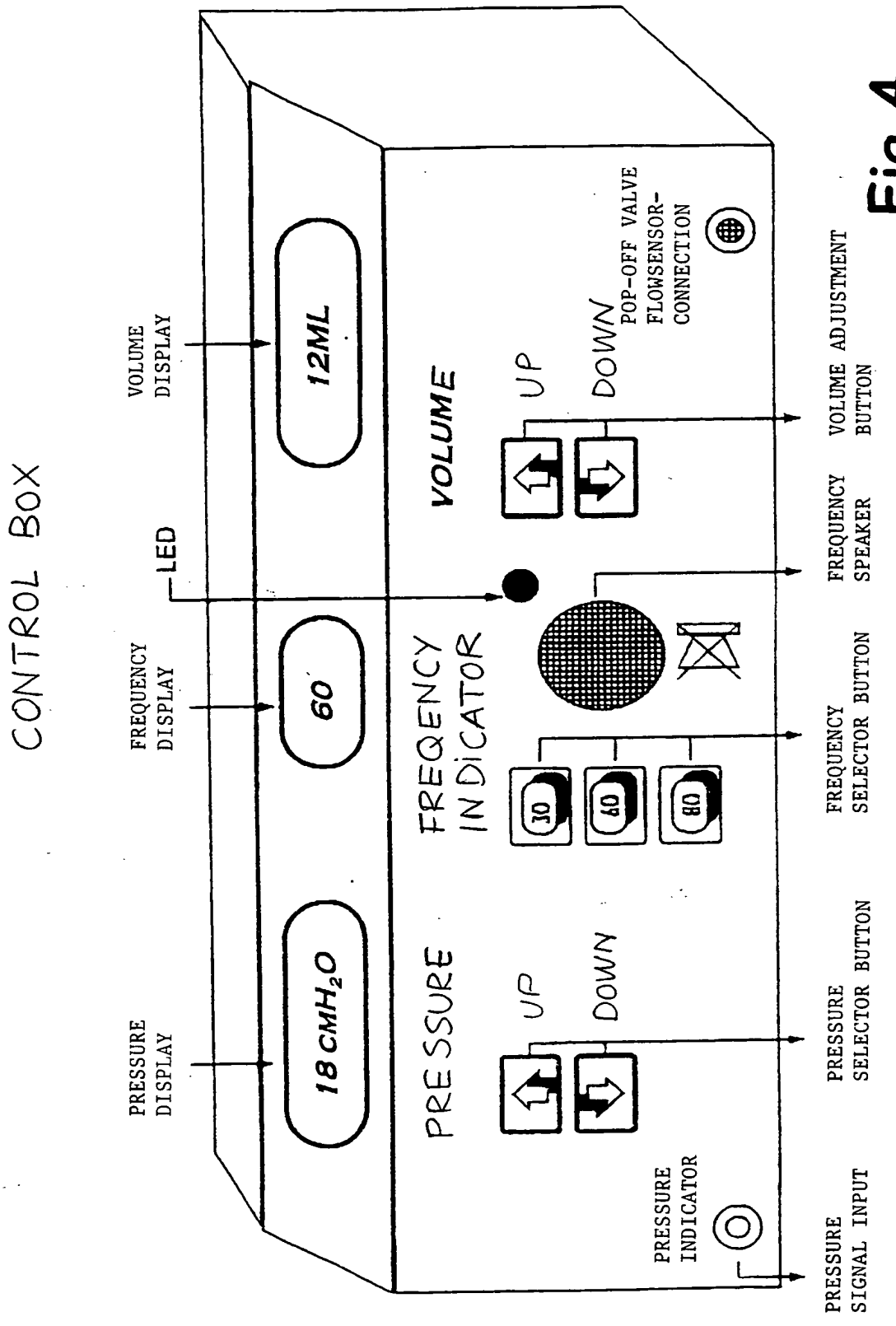

CONTROL BOX
PRESSURE DISPLAY
18 CMH2O
FREQUENCY DISPLAY
60
VOLUME DISPLAY
12ML
LED
PRESSURE
UP
DOWN
FREQENCY INDICATOR
VOLUME
UP
DOWN
POP-OFF VALVE FLOWSENSOR-CONNECTION
30
60
80
PRESSURE INDICATOR
PRESSURE SIGNAL INPUT
PRESSURE SELECTOR BUTTON
FREQUENCY SELECTOR BUTTON
FREQUENCY SPEAKER
VOLUME ADJUSTMENT BUTTON

Fig.4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NO 00/00284

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 16/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4196725 A (ARTHUR M. GUNDERSON), 8 April 1980 (08.04.80), figure --	1
X	US 4297999 A (JOHN V. KITRELL), 3 November 1981 (03.11.81), abstract, figure --	1
A	US 5497767 A (SVEN-GUNNAR OLSSON ET AL), 12 March 1996 (12.03.96), abstract, figure --	1
A	US 5875777 A (PER-GÖRAN ERIKSSON), 2 March 1999 (02.03.99), abstract, figure --	1

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 November 2000	05 -12- 2000
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Hélène Erikson/Els Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NO 00/00284

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5931162 A (KLAUS CHRISTIAN), 3 August 1999 (03.08.99), abstract, figure -- --------	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/NO 00/00284

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4196725 A	08/04/80	NONE	
US 4297999 A	03/11/81	NONE	
US 5497767 A	12/03/96	AU 4363293 A	21/11/94
		DE 69323725 D,T	28/10/99
		EP 0621049 A,B	26/10/94
		JP 6285171 A	11/10/94
		SE 470417 B,C	21/02/94
		SE 9300364 A	21/02/94
		WO 9425718 A	10/11/94
US 5875777 A	02/03/99	AU 1048997 A	03/07/97
		EP 0803262 A	29/10/97
		EP 0865708 A	23/09/98
		JP 10033679 A	10/02/98
		SE 9601611 D	00/00/00
US 5931162 A	03/08/99	EP 0811394 A	10/12/97
		JP 10052494 A	24/02/98
		SE 9602199 D	00/00/00